EXHIBIT A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: ***Wave 2 Cases***	

Gynemesh PS Expert Report of Robert M. Rogers, Jr. M.D.

I. Qualifications

I am board certified in Obstetrics and Gynecology since 1986, and since 2013, also board certified in Female Pelvic Medicine and Reconstructive Surgery. Both of these board certifications are currently active. I presently have an active practice of gynecologic surgery and referral urogynecology in northwest Montana, in Kalispell, since the summer of 2005. I recently stepped down as the chief of the Department of Gynecology at the Kalispell Regional Medical Center.

I graduated from Princeton University in 1971 with an A.B. in Chemistry. I then worked for a pharmaceutical company, ALZA, in Palo Alto, California, as part of a team in developing transocular delivery systems for medications for glaucoma. In 1975, I began my medical studies at the University of Lausanne in Lausanne, Switzerland. After two years of study there, I transferred to my sophomore year at Temple University School of Medicine in the Fall of 1977.

I graduated from Temple University School of Medicine in 1980, and then, completed a four year residency in obstetrics and gynecology at The Reading Hospital and Medical Center in June, 1984. From there, I established a solo practice of general obstetrics and gynecology in Western Pennsylvania, in Kittanning at the Armstrong Memorial Hospital. In performing many reparative vaginal surgeries at that time and following up with my patients post-operatively, I realized that the 'traditional' ways of surgically repairing vaginal cystoceles, enteroceles, rectoceles, uterovaginal prolapse, and hypermobile urethra for stress urinary incontinence resulted in a high recurrence of these same vaginal support defects. The surgical results from these procedures, in my experience, had unacceptable failure rates.

After 6 ½ years of practice in Western Pennsylvania in January, 1991, I left Kittanning at the invitation of a group of obstetricians and gynecologists in eastern Pennsylvania in Reading at The Reading Hospital and joined them at The

Women's Clinic, a private practice of 6 doctors. At this point in my career, I actively pursued my interest in the surgical anatomy of the female pelvis, and in the anatomy of urinary and fecal continence and vaginal support. In addition to much reading in textbooks and articles in the gynecologic and anatomic literature, I spent many hours performing cadaveric dissections in the medical student anatomy lab at the Jefferson Medical College in Philadelphia with the gracious permission of Dr. Richard Schmidt, professor of Anatomy and head of the medical student anatomy course and cadaver lab. As my studies and learning evolved, I began to lecture in various subjects in practical gynecologic surgical anatomy at the Reading Hospital, at the University of Pennsylvania department of Obstetrics and Gynecology, at Temple University, and other hospitals and departments of gynecology in eastern Pennsylvania, New Jersey and Maryland. Further, I taught anatomic and surgical instruction to OB/GYN residents from the Reading Hospital and Medical Center and the University of Pennsylvania from 1992 through 2005.

During the early 1990s, I began attending the scientific meetings of the Society of Gynecologic Surgeons. At these meetings, I gave several general session presentations on my anatomic work in gynecologic surgery. In 1995, I was elected to membership. As the result of my association with the Society of Gynecologic Surgeons, I met Drs. Cullen Richardson and Sandra Retzky, both actively involved in the study of female pelvic and vaginal support anatomy. In the summers of 1993 and 1994, we three and Dr. Gene Colburn, a professor of Anatomy at the Medical College of Georgia, spent 3 full days each year in the cadaver dissection lab at Rush Medical College in a pursuit of intense learning. These days were important for all of us in understanding the anatomy of pelvic and vaginal support and the anatomy of urinary and fecal continence. These sessions in conjunction with the anatomic work of Dr. John DeLancey at the University of Michigan produced several chapters and publications on these subjects, which helped to establish the current and accepted anatomic framework used in reconstructive vaginal surgeries performed today. In 1995, Dr. Sandra Retzky and myself wrote a *Ciba Clinical Symposia* (Vol. 47, No. 3, 1995), "Urinary Incontinence in Women." This booklet was one of the first publications with illustrations and explanations of our current knowledge of pelvic and vaginal support anatomy.

At the same time in the middle 1990s, I was invited to Baltimore by Drs. Al Bent, Geoff Cundiff and Harry Johnson, all practicing reparative vaginal surgeons and urogynecologists. Dr. Johnson had the insight to gather laparoscopic instrumentation and unembalmed human cadavers for important and ground breaking anatomic studies. We, together, began to perform laparoscopic surgical dissections at the Maryland Anatomy Board in the basement of the University Of Maryland School Of Medicine. These several sessions of anatomic dissections on unembalmed cadavers, as opposed to the stiffer embalmed bodies we had previously used, opened up a whole new way of learning and teaching surgical anatomy and surgical dissection techniques, which has become a present day standard of surgical teaching and learning in many surgical specialties. We held our first surgical course of anatomic teaching from unembalmed cadavers in Florida in October, 1996. Since then, I have been the program chair for many open, vaginal, laparoscopic and robotic anatomy courses using unembalmed cadavers (please refer to my CV).

Because of my experience in reconstructive/reparative vaginal surgery and my concerns with my failure rates, and those reported in the literature, I began to talk with my colleagues at the meetings of the Society of Gynecologic Surgeons and the AAGL. The AAGL is the largest organization in the world of gynecologic surgeons. This organization emphasizes the study and teaching of minimally invasive gynecologic procedures, such as those performed per vaginum, with the laparoscope, and with the da Vinci robot. In the late 1990s and early 2000s, I spoke with Dr. Tom Julian, Professor of Gynecology at the University of Wisconsin. During our discussions, he mentioned that he was beginning to use a sheet of polypropylene mesh placed in the anterior vaginal compartment in order to increase his success rate of anterior vaginal wall prolapse repair (cystocele repair). He verbally reported to me a very impressive success rate. I was, of course intrigued, and began to investigate the use of mesh in the vagina. He told me, to paraphrase his words, that he would tolerate a 7% mesh erosion rate in order to achieve an almost 100% success rate in repairing patients sent to him with severe cystoceles and recurrent severe cystoceles. He, of course, thoroughly counseled his patients, and they were accepting, as he reported to me.

Because of my expertise in understanding, teaching and performing anatomic dissections on unembalmed cadavers, I was invited by Ethicon to come to New Brunswick, New Jersey to teach vaginal support anatomy and to interact and consult with the research scientists and biomedical engineers in studying new possibilities for products to be used in surgery for repair of vaginal prolapse.

Since the early 1990s to the present, I have had the opportunity to teach various groups of gynecologic surgeons all over the United States and other countries of the world, including Austria, France, Belgium, Canada, South Korea, Japan and Australia. I have organized and taught unembalmed cadaver courses for teaching gynecologic surgical anatomy and surgical dissection techniques for various individual hospitals and academic departments of Gynecology, at various courses for gynecologic surgeons, for Ethicon and for Cook Medical, as well as for large professional organizations of gynecologic surgeons such as the Society of Gynecologic Surgeons, the AAGL, and The Society of Pelvic Reconstructive Surgery. I have had multiple opportunities to lecture with the thought-leaders in this country and in the world in pelvic/vaginal support anatomy and the various reconstructive surgeries, including use of the various Ethicon mesh products.

In the summer of 2005, my wife and I decided to have a change in our lifestyle and move from the East Coast to the West, in order to take advantage of more outdoor recreational activities. I met my present partner, Dr. Richard Taylor, through a mutual friend at the large AAGL Annual Meeting in 2004. Eventually, I did relocate my practice to northwest Montana to Kalispell.

Since I moved to Kalispell, Montana in the summer of 2005, I have established an active practice of gynecologic surgery and urogynecology, with more of my patient referrals and surgery involved with vaginal prolapse repairs and surgery for stress urinary incontinence and fecal incontinence. Since May of 2008, when our office converted to an electronic medical documentation system, I have performed over 700 surgeries, approximately 100 per year, for reconstruction of various vaginal support defects, with several hundred of these cases involved with placement of Gynemesh PS and the Prolift products from Ethicon for support of

the anterior, apical or posterior segments of the vagina. I have performed over 200 midurethral slings on these patients, most of them involving the suprapubic midurethral TVT, TVT-O and TVT-Secur products from Ethicon. I have used both mechanically cut and laser cut TVT meshes and have not detected any clinical difference between the two in my clinical experience or in my review of the medical literature.

I am a member of the American College of Obstetricians and Gynecologists (ACOG), the American Association of Gynecologic Laparoscopists (AAGL), the Society of Pelvic Reconstructive Surgeons (SPRS – dissolved in 2012), and the Society of Gynecologic Surgeons (SGS). In addition to my leadership positions as a member of the Board of Trustees for the AAGL, Board of Trustees and Chairman of the Board for the Society of Pelvic Reconstructive Surgery, Education Committee member for the SGS, and Co-Chair of the Video Review Committee for AAGL, I also serve as a peer reviewer for the Journal of Minimally Invasive Gynecology.

I have published extensively on the conditions and operative anatomy related to urinary incontinence and pelvic organ prolapse, the surgical treatment and complications related to both conditions, as well as training, teaching, and evaluating gynecologic surgeons.

During my career, beginning with my Ob/Gyn residency in 1980, I have performed different surgeries for stress urinary incontinence -- vaginal plication of the pubourethral fascia underneath the urethra; anterior colporrhaphy; needle bladder neck suspensions, such as Stamey; open and laparoscopic Burch procedures; open MMK; pubovaginal slings with biologic grafts; and midurethral synthetic slings, such as TVT retropubic, TVT-O and TVT-Secur from Ethicon. I have performed hundreds of each of these procedures.

Furthermore, during my career, I have performed thousands of surgeries for pelvic organ prolapse, including anterior colporrhaphy, posterior colporrhaphy, enterocele repairs, sacrospinous ligament colpopexy, uterosacral ligament colpopexy, and iliococcygeus colpopexy; bilateral paravaginal defect repairs per

vaginum, open incision into the retropubic space of Retzius, with the laparoscope and with the da Vinci robot -- using the patient's own native connective tissues and with mesh products (Gynemesh PS, Prolift) and with biologic graft materials (Pelvicol, Biodesign/Surgisis). I have used the Gynemesh PS and Prolift mesh products several hundred times in my patients and have had great results. As with all surgeons' experiences, I have had occasional complications intraoperatively (for example, bleeding, or bladder or rectal entry); however, these intraoperative events were recognized and repaired by myself or with surgical consultation. These patients recovered well. Latent complications of urinary voiding dysfunction, postoperative pain or mesh erosion were handled individually depending on the patient's presentation and complaint. These postoperative problems and complications were well within those reported at professional conferences, discussions with my colleagues and in literature articles that I have read during my career.

In summary, over 90% of my own patients are pleased with the long-term results of their reparative vaginal surgeries using the Gynemesh PS and Prolift products. They are comfortable without any vaginal or pelvic pressure, vaginal intercourse is comfortable, especially with use of vaginal estrogen cream and appropriate personal lubricants. They can urinate and empty their bladders and leak none to very little urine with physical stress maneuvers. Their bowel movements are soft and regular and are passed completely without straining. The vast majority when asked are very happy they decided to have their surgery. I see some of these patients because they return to see me with concerns about the lawyers' television advertisements about vaginal meshes. After taking a updated history and performing a physical exam, I am able to further reassure these patients, and of course, they are relieved and pleased with the surgical results. They admit that their quality of life has improved. My professional experience with polypropylene meshes is confirmed by the gyn and urogyn literature. (Svabik et al., ISUOG, 2014; Altman et al., NEJM, 2011; Jacquetin, Int Urogynecol J, 2013)

I attended the TVT National Prof Ed training sponsored by Ethicon on February 1, 1999 with Dr. Vincent Lucente at Lehigh Valley Hospital in Pennsylvania. This

training was comprehensive and very adequate for me to perform the TVT on my own patients safely. Dr. Lucente is an excellent instructor and was always available by phone to answer any of my concerns.

In addition to teaching and lecturing residents, fellows, and colleagues, I also consulted with Ethicon as a Professional Education Preceptor. From 2003 to 2007, I taught a variety of Ethicon courses, such as preceptorships, proctorships, telesurgeries, cadaver labs, and advanced users forums, on products such as the TVT-O, TVT-Secur, Gynemesh PS, and Prolift. I was part of the initial group that went over to learn the TVT-O procedure from Dr. de Leval, and shortly thereafter performed the second TVT-O in the United States.

From the late 1990s to 2007, I was asked by the research and clinical scientists at Ethicon to consult with them on the design and performance of the Prolift, TVT-O, TVT-Secur products, as well as one or two other developing products. I was asked to perform cadaver dissections to be sure that proper surgical dissection techniques would allow proper and safe placement of the various polypropylene mesh products. I was also involved in developing teaching methods for instruction of other pelvic and vaginal surgeons on why and how to use these mesh products, the pelvic anatomy, the properties of the mesh, and the safe and effective use of the products. Ethicon engineers and medical directors also asked for my clinical input and opinions of these products. I found that at Ethicon all my contacts, discussions and work with the research scientists, biomedical engineers and clinicians were consistently respectful, appreciated, and honest. The work environment attitude was always one of 'How can we best help the patient with this problem and eliminate any and all possible risks and potential complications.' I never felt pressure to push a product out. All the product development in which I was involved was thoroughly evaluated and reevaluated step by step, in accordance to the Ethicon standards, the industry standards, and of course, the FDA and federal government standards. There was no room for 'fudging' or manipulating data.

In the fall of 2003, myself, Dr. Vince Lucente, Gyn surgeon from Allentown, Pennsylvania, and the product leader from Ethicon, Mr. Brian Luscombe, traveled

to France and Belgium. [Eth.Mesh.11543627]. In France, we observed Dr. Jacquetin, and then, Dr. Michel Cosson surgically place their version of the hand-fashioned Gynemesh PS product that eventually developed into the Prolift system of repair for vaginal prolapse. We asked the Prolift inventors many questions, looked at their data and observed their surgical techniques. They were very open and honest and frank. As the result of the French experience with native tissue vaginal repairs and their failures, we were told 9 French vaginal surgeons from all over France (the French TVM Group) had been brainstorming and working in close collaboration to develop better techniques for improving postoperative success rates in reconstructive vaginal surgeries. The use of mesh arms to anchor the polypropylene mesh laterally and apically in the pelvis was discovered by the group of 9 French surgeons to be the most secure and safest way to safely ensure better and more durable surgical results. A significant amount of work was done in France and at Ethicon in New Jersey to improve the instrumentation for mesh placement and to establish the best way to place without tension the mesh, the mesh arms and the vaginal and surrounding tissues and organs.

Additionally, in Belgium, we observed Dr. Jean de Leval, the urologist in Liege who developed the TVT-O, perform several of these procedures on his patients with a hypermobile urethra and stress urinary incontinence. Again, we asked many questions and reviewed his unpublished data and clinical experiences. He and his colleagues were open and honest, as well as collegial. Dr. de Leval after lunch asked me to perform a cadaveric dissection for his team. I was pleased to do so, and performed the dissection to demonstrate the vascular and neuroanatomy on the outer portion of the obturator membrane. This dissection convinced me to perform the transobturator sling from 'inside to out' from the vagina. From this dissection, Dr. de Leval published a paper on the anatomy of the TVT-O procedure.

Upon returning to Ethicon in New Jersey, the development of the Prolift products and TVT products continued in earnest with the patients' best interests always at the top of each agenda. The professional education development was always evolving to best teach surgeons on the safe and effective use of Ethicon's

products, on how to competently learn these new procedures, from the printed IFU to lecture presentations to unembalmed cadaver labs. The effort was sincere and thorough. During our lectures and presentations, we always took time to answer questions from the surgeons - whether from the lecture or from individual concerns from their own surgeries with or without the use of any mesh. Surgeons began to come to know Ethicon as a place to go for pelvic anatomy and surgical teaching and training. Didactic slides, discussions, and interactions with the training surgeons involved a discussion of the more common risks associated with the use of the device and generally how to manage common complications.

From my residency training and throughout my career, I have continually learned all about surgical risks and complications. From reading textbooks on gynecologic surgery, such as Te Linde's, and lectures and literature articles, as well as my own surgical experiences and multiple discussions at our Gyn section meetings, I am always thinking of ways to avoid surgical and treatment complications and how to best serve my patients. The development of a surgeon and his or her surgical techniques and improved procedures is an active, continuing process throughout his or her career. Any surgeon who operates will have surgical challenges and have to deal with the occasional complication - intraoperatively and/or postoperatively. As I teach to surgical residents, fellows and practicing surgeons, they will have to deal with surgical risks and complications their entire careers. The vast majority of these are not the result of poor surgical practice. They are the result of patient anatomic variation, or patient response to scarring, or unusually fragile tissues in the field of dissection, or unexpected pathology or medical condition. Pelvic and vaginal surgeons work very closely to the bladder and rectum and work with connective tissue filled with small blood vessels and visceral nerves. The reparative vaginal surgeon must have a three-dimensional working knowledge of a difficult to understand anatomy and use meticulous dissection techniques. This is a challenge for us teachers who teach to teach our colleagues.

Regardless of whether or not certain risks are listed in a manufacturer's IFU, residents, fellows, and surgeons are expected to be familiar with the well-known

complications of gynecologic surgeries, with and without the use of mesh or graft materials. Likewise, residents, fellows, and pelvic floor surgeons are expected to review the medical literature and be aware of the frequency and severity of the complications for the procedures they perform. Similarly, medical students, residents, fellows, and surgeons do not rely on IFUs to learn about the risks and the frequency and severity of complications associated with native tissue repairs, such as anterior/posterior colporrhaphies or sacrospinous ligament fixations, as these procedures are not accompanied with an IFU. Residents, fellows, and pelvic floor surgeons are expected to be familiar with mesh properties, such as pore size and tensile strength, as well as complications associated with foreign bodies, such as vaginal mesh repairs or abdominal sacralcolpopexies.

II. Materials Reviewed

This report contains a summary of my qualifications, education, training, and experience, as well as my opinions based on my education, training, clinical experience, lectures, editorial experience, ongoing review of the medical literature, experience teaching other residents, fellows, and surgeons about surgical procedures, anatomy, and complications, as well as my discussions with colleagues, attendance at various professional society and continuing medical education events, and other materials and literature I have reviewed that are referenced in my reliance list. Such materials include, but are not limited to, the product IFUs, patient brochures, professional education slides, DVDs, and Surgeon's Resource Monograph, as well as internal company design documents, and plaintiffs' expert reports and the reliance materials referenced in the body of those reports. All of my opinions are held to a reasonable degree of medical and scientific certainty. I reserve the right to supplement my report if I receive additional information after signing this report.

III. Fees and Expert Testimony

Chart reviews, writing expert reports, phone consultations: $500 per hour

Face-to-face meetings with lawyers for deposition and trial preparations:
$750 per hour

Attendance at Depositions in Kalispell, Montana: $1000 first hour,
Thereafter -- $ 750 per hour

Deposition Attendance outside of Kalispell, Montana
and Trial Attendance: $6000 per day
Plus travel expenses

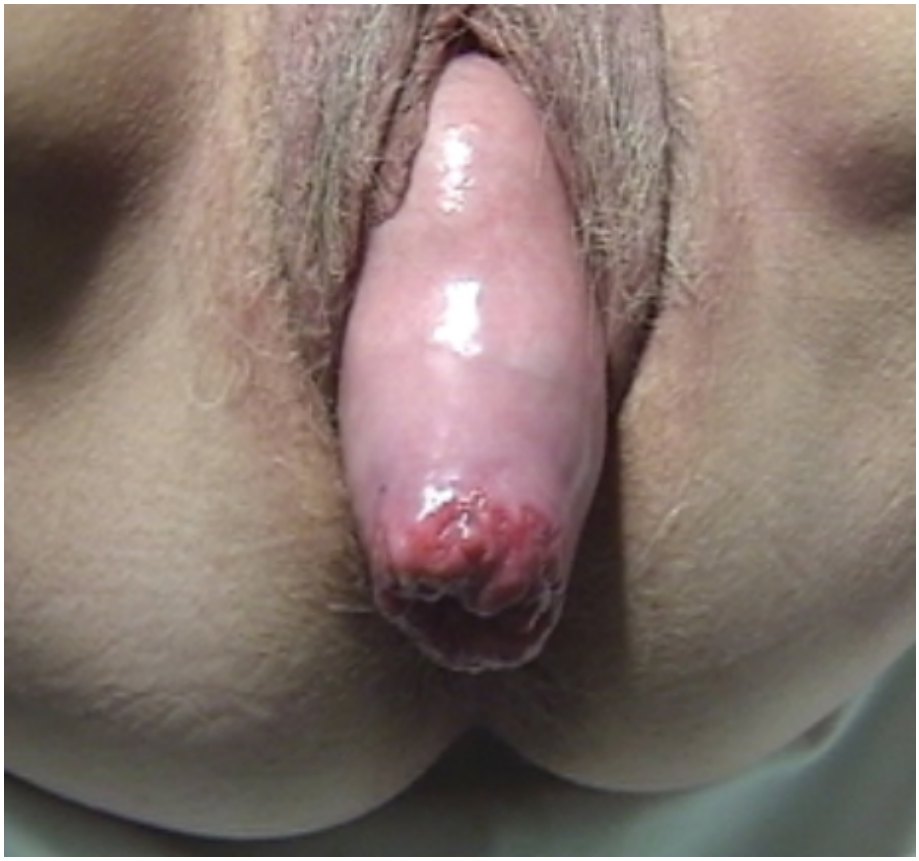
I have provided expert testimony in the following cases within the last four years:

- *Craigg vs. Harris-Stansil* (Superior Court of California, County of San Joaquin)
- *Vicari vs. Schwartz* (New Jersey)
- *Quincy vs. Teel* (Northern California)

IV. Pelvic Organ Prolapse

Pelvic organ prolapse is the result of the physical failure of the vaginal and pelvic support connective tissues and pelvic musculature to maintain the normal anatomic positions in the female pelvis of the bladder, urethra, uterus and cervix, vaginal apex, rectum and anal canal, and perineal body. The proper anatomic positioning of these organs and support structures in the pelvis and their proper anatomic relationships with each other are a prime factor in their proper and normal physiologic functioning. As examples, anatomic prolapse of the anterior vaginal wall results in a cystocele, which is anatomic displacement of the bladder from its normal position, and can result in kinking of the urethrovesical junction and lead to incomplete voiding and bladder emptying. A prolapsed urethra leads to a hypermobile urethra which often causes bothersome stress urinary incontinence and leakage of urine with normal daily activities or exercise. Tearing of the rectovaginal septum of visceral connective tissue between the vagina and rectum leads to a posterior vaginal wall prolapse or rectocele, which causes incomplete evacuation of a bowel movement. Many women in this situation find

the need to take their fingers and push on the perineal body or push back on the vaginal protrusion in order to more completely evacuate their bowel movement. Many times, these women are embarrassed because they cannot completely clean themselves after having a bowel movement. These women learn on their own where bathrooms are located when they shop or travel. They cut back on important liquid consumption in order to decrease urinary leakage. They very commonly avoid social situations and normal daily activities in order to not embarrass themselves.



Women with vaginal prolapse present to the family doctor or gynecologist with complaints of very bothersome, uncomfortable pelvic pressure and pain with severe 'pulling' sensations on the vagina. They complain of feeling like their "insides are coming out of my vagina," or that, "I am always sitting on a tennis ball." Many of these women complain of urinary leakage, or incomplete bladder

emptying, or difficulty with bowel movements. For this reason they actively seek relief for their many complaints. Approximately 1 in 9 women will have at least one surgery for vaginal prolapse or urinary incontinence (Olsen et al., Obstet Gynecol 1997). However, it is reported that in the general female population in the United States that 23.7% of non-pregnant women 20 years old or older have at least one pelvic floor disorder, such as vaginal prolapse, urinary incontinence or fecal incontinence (Nygaard et al. JAMA, Sept. 17, 2008).

The 'old thinking' (what gynecologists were taught before the years of 1995 to 2000) was that vaginal prolapse was the result of stretching or attenuation of the visceral connective tissues that support the bladder, urethra, rectum and vagina. Therefore, repair of vaginal prolapse entailed plication or compensatory 'bunching up" of these connective tissues centrally, using absorbable sutures such as chromic catgut or polyglactin. These older methods of performing reconstructive vaginal surgery had an unacceptable failure rate of 30-50% in my experience and in the published literature. (Olsen et al., Obstet Gynecol 1997) Reoperation rates were as high as 50%. (Clark AL et al. Am J Obstet Gynecol. 2003)

Our current anatomic thinking states that these failures are most commonly the result of tearing of the pelvic/vaginal support visceral connective tissues. The process of connective tissue tearing most commonly occurs from pregnancy, and especially, vaginal childbirth; chronic constipation and straining to have a bowel movement; and activities involving heavy lifting and physical straining, such as physical labor and high impact aerobics. Some patients are born with weakened visceral support connective tissues, or further weaken their connective tissues by cigarette smoking. These visceral connective tissues stretch a little, and then break or tear away from the more supportive pelvic support structures, such as the parietal fasciae of the pelvic sidewall (obturator internus muscles and iliococcygeus muscles), levator ani muscles posteriorly and the uterosacral and cardinal ligaments apically. (Rogers, chapter 'Anatomy of Pelvic Support,' in Ostergards Urogynecology, 2003).

I was well trained in the traditional methods of surgical repairs of vaginal prolapse using the patient's own native connective tissues and support structures – anterior colporrhaphy, posterior colporrhaphy, and enterocele repair by obliteration of the cul-de-sac. However, I soon learned that failures of the native tissue surgical repairs and recurrences of the vaginal prolapse were not uncommon. This was not only caused by inaccurate anatomic teaching and incorrect surgical thinking at that time, before 2000, but also due to the poor visceral connective tissues found in women with vaginal support defects (Ulmsten, Acta Obstet Gynecol Scand, 1987).

With the new anatomic concepts of 'site-specific' breaks in the visceral connective tissues after the period of 1995 to 2000, more reparative vaginal surgeons began to stop the plication of visceral connective tissues in the midline, and began to repair these fascial breaks with permanent sutures to the lateral paravaginal parietal fasciae overlying the obturator internus muscles; to the lateral pararectal iliococcygeus muscle; and to the apical uterosacral ligaments, and occasionally the sacrospinous ligaments. However, failures were still present. At that time, it was felt that weakened visceral connective tissues and physical stress factors were at play in causing the failure of our new anatomic vaginal repairs. In the search for more reliable procedures to repair vaginal prolapse and hypermobile urethra, clinical researchers tried man-made materials, such as polypropylene meshes to further support 'weakened' pelvic connective tissues.

SURGICAL TREATMENTS FOR PELVIC ORGAN PROLAPSE:

Use of Mesh in GYN Surgery

Surgical mesh has been used for decades in hernia and gynecologic surgeries. In 1997, Iglesia and colleagues published a review on the use of mesh in gynecologic surgery. [Iglesia, Int Urogynecol J, 1997] Iglesia et al. described how the "use of synthetic biocompatible materials has become more common in gynecologic surgery over the past three decades. These materials may be used when the surgeon wishes to avoid an additional fascial-harvesting procedure or to use

materials that are stronger than the patient's own fascial tissue." Iglesia et al. described polypropylene mesh as a "strong, non-absorbable monofilament material that is highly elastic and able to withstand infection." In the 1960s and 1970s, hernia and pelvic floor surgeons began publishing their results using synthetic meshes, such as Mersilene and Marlex mesh, for hernia, stress urinary incontinence, and prolapse repairs. [Lane 1962, Moir 1968, Usher 1970, Morgan 1970, Nichols 1973, Stanton 1985, Young 1995, Falconer 2001 etc.]. Iglesia's 1997 review describes the materials and complications that were reported with the use of various synthetic materials in gynecologic surgeries, including but not limited to: vaginal erosion/exposure, removal for infection, dyspareunia, urethrovaginal fistula, mesh rejection, mesh removal for erosion/infection, vaginal/abdominal sinus tracts, sling revisions, stitch abscess, revision for retention, Prolene suture exposures, suprapubic abscess, bladder erosion, voiding dysfunction, and midvaginal band. These risks were and are commonly known to pelvic floor surgeons performing graft-augmented repairs for prolapse and incontinence.

High recurrence rates reported with native tissue prolapse repairs led surgeons to seek more durable surgical interventions with the use of graft materials to augment prolapse repairs. [Abed, Int Urogynecol J, 2011; Weber, AJOG, 2001; Whiteside, AJOG, 2004; Olsen, Obstet Gynecol, 1997]. The SGS Systematic Review noted that "[t]he use of graft augmentation in prolapse repair came as a necessity from the significant failure rates with native tissue repairs." [Abed 2011]. For example, Weber, Walters and colleagues published their results from a 2001 RCT and found that only 30% of patients assigned to the native tissue anterior colporrhaphy group experienced satisfactory or optimal anatomic results at median follow-up of 23.3 months. [Weber 2001]. Whiteside and colleagues described how the anterior vagina is regarded as the vaginal site that is most prone to recurrent prolapse [citing Shull 2000], and found that 58% of women undergoing anterior colporrhaphy had recurrent prolapse of greater than or equal to stage II. one year after surgery. An epidemiological study by Wu and colleagues found that by the age of 80 years old, one in eight women will undergo surgery for pelvic organ prolapse. [Wu, Obstet Gynecol, 2014]. The "estimated

risk of surgery for either SUI or POP in women is 20.0% by the age of 80 years." [Wu 2014].

Mesh-augmented repairs show statistically significant improvement in anatomic cure rate compared to native tissue repairs. [Jacquetin, Int Urogynecol J, 2013].

Int Urogynecol J

Table 1 Randomised controlled trials comparing polypropylene mesh with traditional native vaginal tissue repairs

Reference	Total number patients	Follow up (months)	Compartment studied	Anatomic cure mesh (%)	Anatomic cure traditional (%)	*p*
Hiltunen et al. [9]	104	12	Anterior	93	62	<0.04
Sivaslioglu et al. [10]	90	12	Anterior	91	72	<0.05
Nieminen et al. [11]	105	24	Anterior	89	59	<0.05
Nguyen and Burchette [12]	75	12	Anterior	87	55	<0.05
Carey et al. [13]	139	12	Anterior Posterior	81	65.6	0.07
Nieminen et al. [14]	202	36	Anterior	87	59	<0.0001
Withagen et al. [15]	194	12	All	90	55	<0.001
Altman et al. [16]	389	12	Anterior	82	48	0.008
Sokol et al. [17]	65	12	All	38	30	0.45

Medical Literature Supporting the Safety and Efficacy of Gynemesh PS:

Level one evidence, such as meta-analyses, systematic reviews, and randomized controlled trials, consistently show that prolapse repairs with Gynemesh PS are safe and effective. A 2016 Cochrane Review by Maher et al. reviewed 37 RCTs (4,023 women) and analyzed permanent mesh versus native tissue repair, absorbable mesh versus native tissue repair, and biologic graft versus native tissue repair. [Maher, Cochrane Library, 2016]. This 2016 Cochrane Review analyzed 25 RCTs comparing polypropylene permanent mesh versus native tissue, of which 17 RCTs compared anterior compartment repairs and 8 RCTs compared multi-compartment repairs. [Ali 2006; Al-Nazer 2007; Altman 2011; Carey 2009; da Silveira 2014; Delroy 2013; De Tayrac 2008; De Tayrac 2013; Gupta 2014; Halaska 2012; Iglesia 2010; Lamblin 2014; Menefee 2011; Meschia 2004; Nguyen 2008; Nieminen 2008; Qatawneh 2013; Rudnicki 2014; Sivaslioglu 2008; Svabik

2014; Tamanini 2014; Thijs 2010; Turgal 2013; Vollebregt 2011; and Withagen 2011].

In the permanent mesh vs. native tissue analysis, the 2016 Cochrane Review found that: "Awareness of prolapse at one to three years was less likely after mesh repair; Rates of repeat surgery for prolapse were lower in the mesh group; There was no evidence of a difference between the groups in rates of repeat surgery for incontinence; Recurrent prolapse on examination was less likely after mesh repair; and [t]here was no evidence of a difference between the groups in rates of de novo dyspareunia." However, when factoring in treatment for mesh exposures, the authors noted that "[m]ore women in the mesh group required repeat surgery for the combined outcome of prolapse, stress incontinence, or mesh exposure." This is not surprising given the risk of mesh exposure with any foreign body; however, this risk is well known to pelvic floor surgeons and is most often easily managed or asymptomatic.

The Maher 2016 Cochrane Review looked at 19 RCTs with 1-3 year follow-up and found an overall mesh exposure rate of 12%, with a mesh exposure rate of 10% in the anterior repair only studies. This is consistent with Maher and colleagues 2011 updated Cochrane Review which evaluated 40 RCTs and found that "Native tissue anterior repair was associated with more anterior compartment failures than polypropylene mesh repair as an overlay or armed transobturator mesh." [Maher, Surgical Management of pelvic organ prolapse in women: the updated summary version Cochrane Review, Int. Urogynecol J,2011]. Further, Maher's updated 2011 review found that "There were no differences in subjective outcomes, quality of life data, de novo dyspareunia, stress urinary incontinence, reoperation rates for prolapse or incontinence, although some of these data were limited." Similar to the 2016 Cochrane Review, Maher's 2011 updated review reported a 10% mesh erosion rate.

Dietz and Maher published a review on the impact of pelvic organ prolapse surgery on sexual function. [Dietz, Int Urogynecol J, 2013]. They found that in the anterior compartment, "the use of mesh is associated with neither a worsening in

sexual function nor an increase in de novo dyspareunia compared to traditional anterior colporrhaphy."

Maher's 2013 systematic review of the safety and efficacy of anterior vaginal compartment pelvic organ prolapse surgery concluded that "Consistent level 1 evidence demonstrates superior subjective and objective outcomes following anterior transvaginal polypropylene mesh as compared to anterior colporrhaphy (grade A)." [Maher, Int Urogynecol, 2013].

Similarly, Barber and Maher published a review on the safety and efficacy of pelvic organ prolapse for vaginal apical prolapse surgery and concluded that "Polypropylene mesh is the preferred graft for ASC," and that "Vaginal procedures for vault prolapse are well described and are suitable alternatives for those not suitable for sacral colpopexy." [Barber, Int Urogynecol J, 2013]. Reoperation rates for sacrospinous ligament fixations ranged from 1.3 to 37%.

Additionally, Abed and colleagues, for the Systematic Review Group of the Society of Gynecologic Surgeons, published a systematic review in 2011 on the incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials. [Abed 2011]. The SGS Systematic Review found an overall mesh erosion rate of 10.3% described in 110 studies, and an overall dyspareunia rate of 9.1% reported in 70 studies. These rates were similar between synthetic and biologic grafts. Abed 2011 found that most graft erosions occur within 1 year of surgery, typically presenting with symptoms of "vaginal discharge, vaginal pain, and/or dyspareunia," although few more erosions can be detected with longer follow-up. The SGS review found that risk factors for vaginal graft erosion were "increasing patient age and concomitant hysterectomy and/or rectocele repair at the time of vaginal prolapse repair." While some studies cite lower intervention rates for managing mesh exposures, especially when they are asymptomatic, the SGS review found that "the majority of symptomatic mesh erosions (67%) required surgical excision either in the office or in the operating room." The SGS Systematic Review noted that dyspareunia and granulation tissue formation are not unique to mesh repairs, as "native tissue

repairs may be complicated by dyspareunia and granulation tissue formation in a similar manner to what occurs with graft-augmented repairs."

Feiner and colleagues performed a systematic review in 2008 to evaluate the efficacy and safety of transvaginal mesh kits in the treatment of prolapse at the vaginal apex in 30 studies (2,653 women), and found that the "overall objective success using transvaginal mesh kits in restoring apical vaginal prolapse is high." [Feiner, BJOG, 2008]. Mesh erosions were the most commonly reported complication, occurring in 4.6-10.7% of women. Reoperations requiring anesthesia occurred at a rate of 1.5-6%, and reoperations not requiring anesthesia occurred at a rate of 0.4-2.3%.

Jia and colleagues performed a systematic review and meta-analysis evaluating the efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse in 49 studies involving 4,569 women. [Jia, 2008, BJOG]. Their review showed that "Nonabsorbable synthetic mesh had a significantly lower objective prolapse recurrence rate (8.8%, 48/548) than absorbable synthetic mesh (23.1%, 63/273) and biological graft (17.9%, 186/1,041), but a higher erosion rate (10.2% 68/666) than absorbable synthetic mesh (0.7%, 1/147) and biological graft (6.0%, 35/581)." The authors noted that "Mesh or graft repair is theoretically suitable for any degree of symptomatic anterior and/or posterior vaginal wall prolapse."

Diwadkar and colleagues performed a systematic review in 2009 to evaluate complication and reoperation rates after apical vaginal prolapse surgical repair. [Diwadkar, ACOG, 2009]. Dyspareunia rates for traditional vaginal repairs, sacral colpopexy repairs, and mesh kits were similar at 1.5%, 1.5%, and 2.2%, and pain rates were 1.6%, 2.3%, and 2.5%, respectively. Total complication rates were also similar.

Sun and colleagues compared patient outcomes of mesh repair and colporrhaphy for the treatment of anterior vaginal wall prolapse involving 11 studies (1,455 patients). [Sun, Int Urol Nephrol, 2016]. Sun et al. found no significant differences for the following complications: urinary retention, urinary

incontinence, voiding difficulty, dyspareunia, urinary tract infection, and vaginal bulge. They concluded that "Surgical repair with the mesh procedure appears to be a better choice for the treatment of anterior vaginal wall prolapse."

Adequacy of IFU, Patient Brochures, and Prof Ed Training

I have reviewed the Prolift 2005 and 2007 Professional Education slides, DVDs, and the 2007 Prolift Surgeon's Resource Monograph. These educational materials provide trainee surgeons with an in depth discussion of other surgeons' experiences and literature on success, failure, and complication rates, as well as risk factors, mesh properties, surgical technique pearls or procedural tips, and information on minimizing and treating complications. For example, the complications described in the Prolift Surgeon's Resource Monograph include thorough discussion on: hemorrhage, hematoma, fistula, infection, urinary retention, mesh exposure, mesh erosion, dyspareunia, and vaginal pain.

In addition, I have reviewed the Gynemesh PS IFUs, and it is my opinion that the IFUs appropriately warn experienced pelvic floor surgeons who perform prolapse procedures about the risks associated with the use of the mesh. [Eth.Mesh.02342194, Eth.Mesh.02342278, Eth.Mesh.02342250, and Eth.Mesh.02342218]. The Adverse Reactions section of the Gynemesh PS IFUs warned surgeons that: "Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, and extrusion." In 2005, the Gynemesh PS IFU was updated to include "scarring that results in implant contraction" in the Adverse Reactions section. All of these risks are all commonly known risks that medical students, residents, fellows, and board certified pelvic floor surgeons are expected to already know, including the frequency and severity of those complications. Additional risks that are not included, such as those suggested by plaintiffs' experts that should have been included in the IFU, are commonly known, obvious risks for the surgeons performing these surgeries, and do not need to be included in the IFU. [21 CFR 801.901(c)]. A scalpel is a medical device, but surgeons do not need to be warned

of the obvious risk that a scalpel can potentially cause bleeding. Throughout my career I have reviewed a significant number of IFUs for various manufacturers' products, and I have not come across an IFU that lists specific complication rates (i.e., frequency and severity) for the adverse reactions sections of the various IFUs. For example, it is well known that that any pelvic floor surgery can cause de novo dyspareunia. It is an unavoidable risk that is commonly known and is not unique to mesh surgeries. Postoperative dyspareunia after POP repair without mesh in the posterior compartment has been reported to approach 40%. [Weber, AJOG, 2000]. Lowman reported on de novo dyspareunia rates for various POP procedures with and without mesh as shown below. [Lowman, AJOG, 2008]

TABLE 4
De novo dyspareunia after prolapse surgery

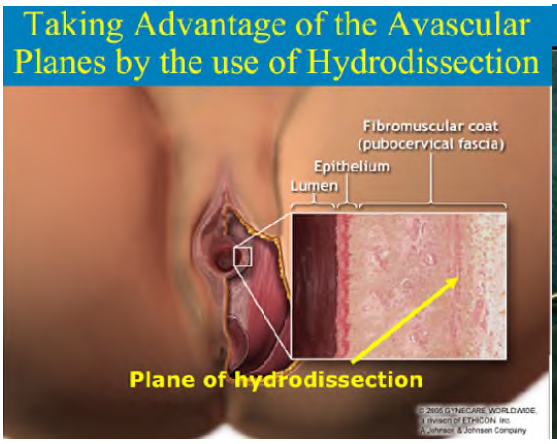
Dyspareunia	ASC N = 224 (148)[a] Handa et al[21]	SSLF N = 287 (106)[a] Maher et al[6]	USS N = 110 (34)[a] Silva et al[27]	APR N = 165 (81)[a] Weber et al[18]	Prolift N = 129 (57)[a]
Baseline (preop) dyspareunia (%)	40.5 (60/148)	Unknown	20.6 (7/34)	8.0 (6/81)	36.8 (21/57)
De novo (postop) dyspareunia (%)	14.5 (11/76)	36.1 (22/61)	25.9 (7/27)	19.0 (14/75)	16.7 (6/36)

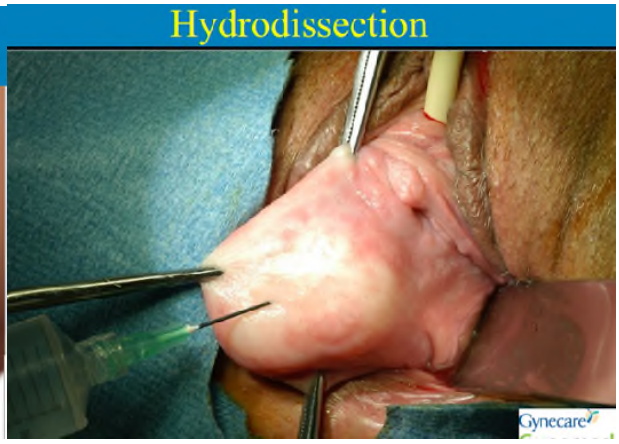
[a] Number sexually active preop.

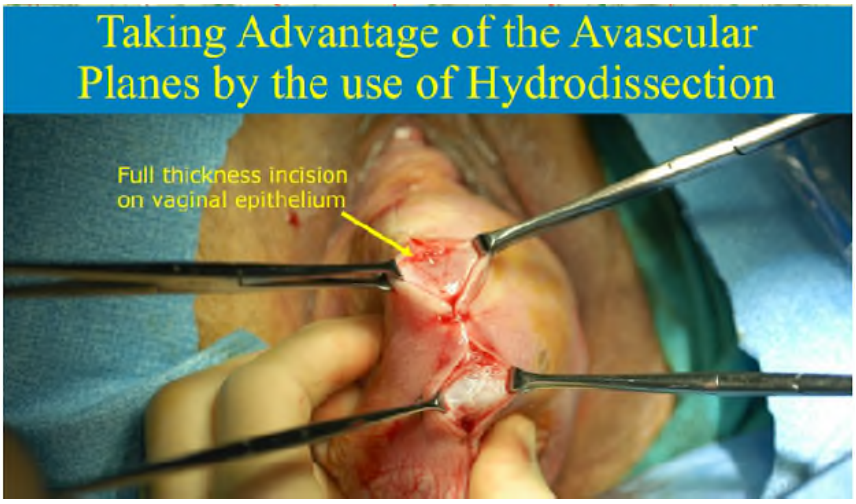
I participated in a Master Surgeon's Roundtable titled, "Dissection Techniques in Transvaginal Pelvic Organ Prolapse Repair with Synthetic Mesh: A discussion of vaginal dissension techniques using hydrodissection," along with my colleagues, Drs. Jayne, Lucente, and Sepulveda. As part of this discussion, we described the complications that can result from surgeon technique, such as performing a split thickness dissection as opposed to a full thickness dissection when implanting mesh transvaginally. Dissection steps, including hydrodissection, sharp dissection, and blunt dissection helps to separate the bladder from the vaginal tissue, thereby reducing the risk of mesh exposure by allowing the surgeon to more easily access the avascular space in which the mesh should be placed. In

fact, Dr. Sepulveda noted that "no significant vaginal surgery can be done without hydrodissection."

Hydrodissection Technique				
	Jayne	**Lucente**	**Rogers**	**Sepulveda**
Fluid	1% lidocaine with epinephrine diluted 3:10 with normal saline	0.25% lidocaine diluted 1:1 with normal saline	0.25% marcaine diluted 1:1 with normal saline	2% lidocaine with epinephrine diluted 1:4 with normal saline
Total volume per dissected compartment	90-120 cc	60 cc	80 cc	120 cc
Midline volume	30-60 cc	20 cc	20 cc	40 cc
Lateral volumes (each)	30 cc	20 cc	30 cc	40 cc



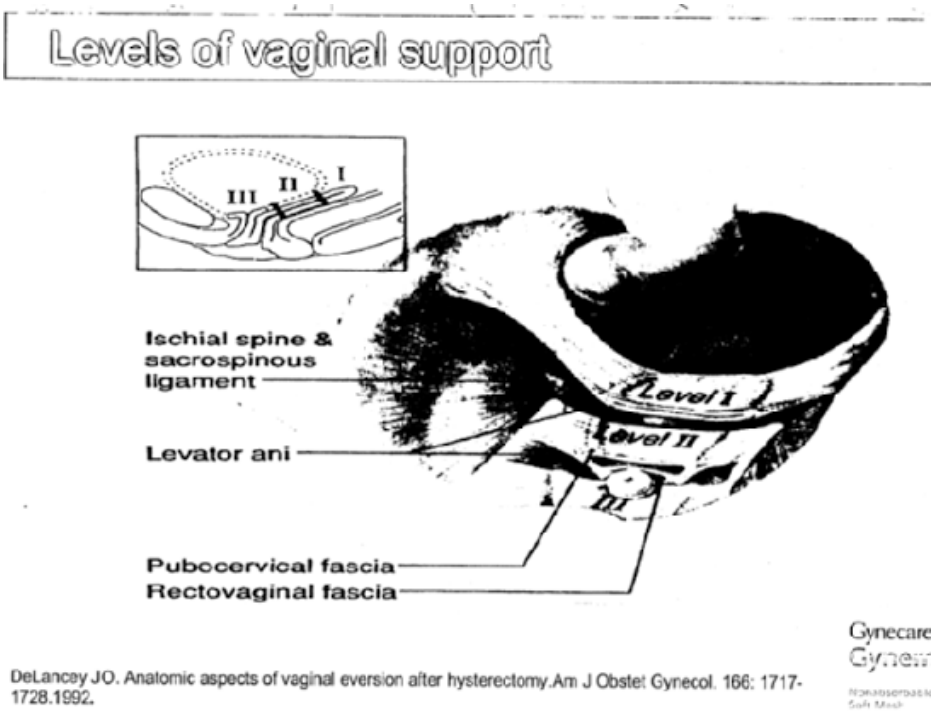




Also, we described how surgeon experience can impact complication rates. For example, in my first year using the Prolift, my exposure rate was 4.6%, but later dropped down to 1%. [*See also* Achtari, Int Urogyn J, 2005; Welk, JAMA, 2015; Berrocal, J Gynecol Obstet Biol Reprod, 2004; FDA Public Health Notification, 2008]]. Similarly, Dr. Lucente noted that surgical skills are honed with practice, and reported his mesh exposure rate with Prolift as being 2.4%. He explained that "[m]ost exposures will occur at the incision, so limiting length [of the dissection] can help reduce the risk of mesh exposure."

Additionally, I have reviewed the Gynemesh PS Professional Education materials [Eth.Mesh.00159266, Eth.Mesh.10038839, Eth.Mesh.00018344]. The Gynemesh PS Pelvic Floor Surgery and Anatomic Dissection Lab slides included the following educational objectives: (1) Explain the rationale to use Gynemesh PS based on histological and anatomical evidence; (2) Establish the indications for reductive plication repairs compared to augmented repairs with Gynemesh PS; (3) Review briefly the characteristics of Gynemesh PS and its interaction with prolapsed tissue; (4) Illustrate the technique used in the placement of Gynemesh PS; and (5) review the management of complications associated with the use of Gynemesh PS. Ethicon instructed surgeons on the risk factors for POP, which include: age, menopause, parity, genetics, neuropathy and myopathy, obesity, smoking, activity, and previous pelvic surgery. [Weber, Obstet Gynecol, 2005]. The Gynemesh PS Professional Education slides include a discussion of prolapse

anatomy, risk factors, and epidemiology. For example, 29-40% of prolapse surgery is for recurrence [Olsen 1997]; 60% same site recurrence [Marchionni 1999], and 32.5% of recurrences occur at different sites due to unmasking of occult support defects [Clark 2003].



Surgical repairs for prolapse include obliterative repairs, such as the Le Fort Colpocleisis procedure, which provides anatomical support by closing the vaginal canal. This procedure eliminates any functional potential of the vagina and should therefore only be performed on patients who permanently do not plan to engage in sexual intercourse. Another procedure is called plication repairs, such as anterior and posterior repairs or Kelly plications. These repairs use sutures instead of grafts and are intended for level III defects. Augmented repairs using mesh kits and grafts sutures to support structures are another treatment option for prolapse, providing level II and III support. These augmented repairs rely on

tissue ingrowth into the graft to provide a more durable repair. Optimal characteristics of non-absorbable grafts used for vaginal repairs include: low volume, monofilament, porosity, durability, and ease of identification if removal is required (e.g., blue pigment used in Gynemesh PS).

Types of Graft with Potential use in POP Repair

Type of Graft	Graft Properties
Autogenic (from subject)	Harvesting, incision, morbidity. Limited by size.
Allogenic (Cadaveric)	High cost. Inconsistent quality. Degradation at 12 months. Limited by size.
Xenogenic (Animal source)	Degradation at 18 mo. Risk of seroma. Somewhat limited by size.
Synthetic	Allows for lightweight reproducible quality without size limitations.

The ideal mesh properties are widely recognized across the medical profession as consisting of an Amid type I polypropylene, monofilament, open weave (large pore is defined as being greater than 75 microns). [Amid, Hernia, 1997]. The widest pore measurement of Gynemesh PS is commonly described as being 2,400 to 2,500 microns, which is significantly larger than the 75 microns suggested by Amid's 1997 landmark classification designed to allow sufficient tissue ingrowth and resist infection. This is consistent with Deffieux's 2012 guidelines for clinical practice, which states that "it is recommended to use a macroporous polypropylene monofilament mesh" if a synthetic mesh is placed vaginally or through laparoscopic sacralcolpopexy. [Deffieux, European Journal of Obstetrics & Gynecology and Reproductive Biology, 2012].

Amid Classification of Mesh

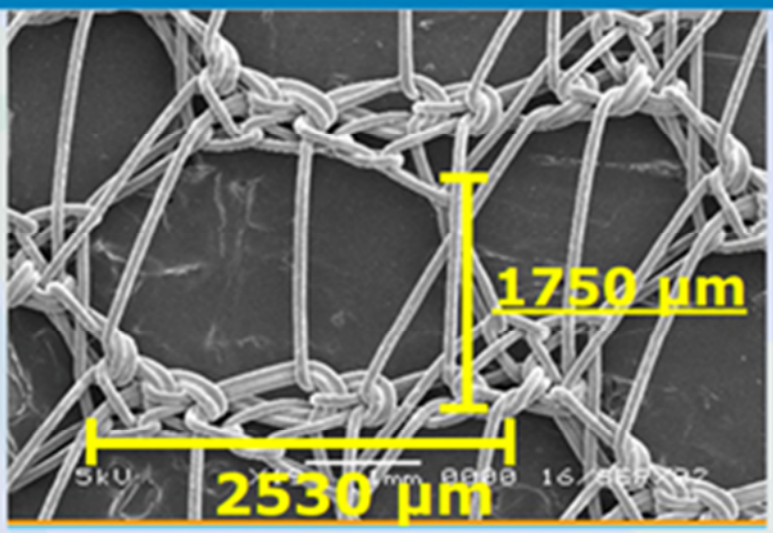
Type	Pore size	Description
1	At least 75 microns	Macroporous
2	Less than 10 microns	Microporous
3	Above 75 microns with interstices less than 10 microns	Macroporous with multifilament component
4	Less than one micron	Submicronic

*GYNECARE GYNEMESH PS pore size is 1750 microns X 2530 microns.

Deprest et al. Int Urogynecol J 2006;17:S16-S25

Gynecare Gynemesh PS

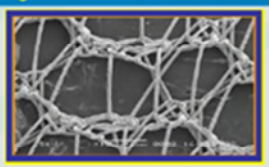
Pore Size of GYNECARE GYNEMESH PS



Macroporous is defined as at least 75µm

Gynecare Gynemesh

Synthetic Grafts Non-Absorbable: *Weave*

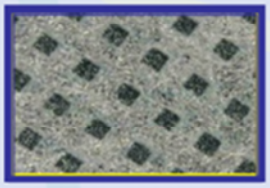


Knitted

- Highest porosity
- Lowest volume
- Largest interstices

Woven

- Microporous component
- Larger volume



Non Woven Non Knitted

- Microporous
- Highest Volume

Gynecare Gynemesh PS

How Does GYNECARE GYNEMESH PS Compare to the Most Used Non Absorbable Grafts?

Characteristic	GYNECARE GYNEMESH PS (Polypropylene)	PROLENE Mesh (Polypropylene)	MERSILENE* Polyester Fiber Mesh
Thickness (in)	.016	.019	.010
Weight (mg/cm^2)	4.36	7.60	4.22
Porosity (% of total area)	65.6	53.1	62.7
Flexibility (mg/cm^2)	176.71	623.53	17.41

GYNECARE GYNEMESH PS Early clinical experience. White paper.

Gynecare Gynemesh PS

Residents are expected to understand the categories of graft materials, including synthetic polypropylene meshes. [AUGS Resident Learning Objectives]. Residents are also expected to understand the vital characteristics of synthetic grafts, such as pore size, monofilament vs. multifilament, and materials type. Further, they are expected to understand the relative indications for, and complications associated with, each category of grafts, as well as understand the management of graft complications, both surgical and non-surgical. I was an author on the Gynemesh PS white paper, in which we described the importance of the mesh design in choosing a mesh to implant in a patient. [Gynemesh PS White Paper]. We discussed how mesh characteristics can play a role in contributing to mesh erosions: "Several factors are thought to contribute to mesh erosions including a poor healing environment influenced by nutritional status and blood flow, infections, foreign body reactions, and mesh characteristics such as rigidity, mesh density, and mesh porosity. In choosing or designing a synthetic mesh for use in pelvic floor repair, it is necessary to consider certain characteristics. First, it is important to consider rigidity/flexibility.... The density and weight of the mesh are also important factors... Another important property of synthetic meshes is strength. A mesh must have the necessary tensile and bursting strength to provide the extra support that is needed to prevent recurrence of prolapse.... Pore size is also an important characteristic, as it not only relates to handling properties but also to the ability of the mesh to interact with the tissues in which it is implanted." We found in the vaginal vs. abdominal Gynemesh PS White Paper Study that "Gynemesh PS appears to be an acceptable material for the repair of POP. The improved mesh characteristics, which include a less rigid polypropylene polymer and a decrease in total polypropylene content, may contribute to less complicated interventions for mesh exposures."

TABLE 1:
Mesh Characteristics

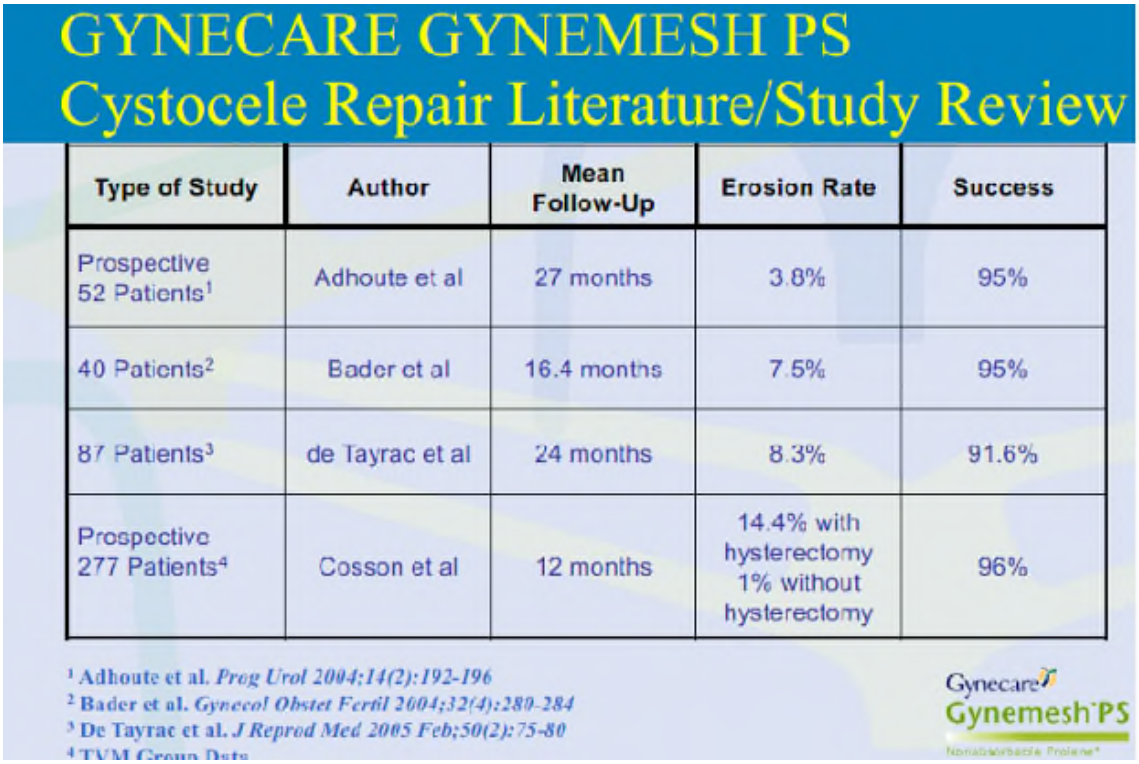
Characteristic	GYNEMESH PS	PROLENE Mesh	MERSILENE Mesh
Thickness (in)	0.016	0.019	0.010
Unit Weight (mg/cm²)	4.36	7.60	4.22
Porosity (% of total area)	65.6	53.1	62.7
Burst Strength (psi)	115.82	234.33	82.92
Flexibility (mg/cm)	176.71	623.53	17.41
Tear Strength (lb)			
W (knitting machine axis)	4.41	7.32	1.23
C (across machine axis)	2.56	9.03	1.27
Suture Pull-Out (lb)			
W (knitting machine axis)	5.96	11.22	2.27
C (across machine axis)	6.55	13.88	2.06
Tensile Strength (lb)			
W (knitting machine axis)	21.67	50.48	26.37
C (across machine axis)	21.78	42.32	13.39

[Gynemesh PS White Paper].

Complications can be attributed to factors including: (1) the surgeon's level of experience; (2) the surgeon's surgical technique; (3) individual patient factors; and (4) the graft material. For example, Achtari and colleagues published in 2005 on risk factors associated with mesh exposure, and found that surgeon experience, hysterectomy, and vertical incisions and plications were all risk factors for mesh erosions or exposures. This is consistent with the surgical reality that just because a patient experiences a complication, it does not mean that the mesh was defective.

In an effort to reduce complications attributed to the surgical technique, Ethicon's Professional Education emphasized the importance of hydrodissection in order to facilitate development of the full thickness vaginal epithelium to cover Gynemesh PS. Ethicon also taught variations of pelvic floor repairs using Gynemesh PS without a mesh kit, such as the tension-free iliococcygeus repair, and with a mesh kit, such as the Prolift device. Ethicon Prof Ed slides discussed the management of complications associated with Gynemesh PS repairs, including: bleeding,

hematoma, vaginal mesh exposures, and sexual dysfunction/dyspareunia. [Deffieux 2007, Achtari 2005, Benhaim 2006].



GYNECARE GYNEMESH PS
Cystocele Repair Literature/Study Review

Type of Study	Author	Mean Follow-Up	Erosion Rate	Success
Prospective 52 Patients[1]	Adhoute et al	27 months	3.8%	95%
40 Patients[2]	Bader et al	16.4 months	7.5%	95%
87 Patients[3]	de Tayrac et al	24 months	8.3%	91.6%
Prospective 277 Patients[4]	Cosson et al	12 months	14.4% with hysterectomy 1% without hysterectomy	96%

[1] Adhoute et al. *Prog Urol 2004;14(2):192-196*
[2] Bader et al. *Gynecol Obstet Fertil 2004;32(4):280-284*
[3] De Tayrac et al. *J Reprod Med 2005 Feb;50(2):75-80*
[4] TVM Group Data

Gynecare Gynemesh PS

GYNECARE GYNEMESH PS
Rectocele Repair Literature/Study Review

Type of Study	Author	Mean Follow-Up	Erosion Rate	Success
Prospective 52 Patients[1]	Adhoute et al	27 months	3.8%	100%
67 Patients[2]	de Tayrac et al	24 months	12%	92.3%
Prospective 277 Patients[3]	Cosson et al	12 months	Less than 1% 0.5%	96%

[1] Adhoute et al. *Prog Urol 2004;14(2):192-196*
[2] De Tayrac et al. *Int Urogynecol J* 2006;17:100-105
[3] TVM Group Data

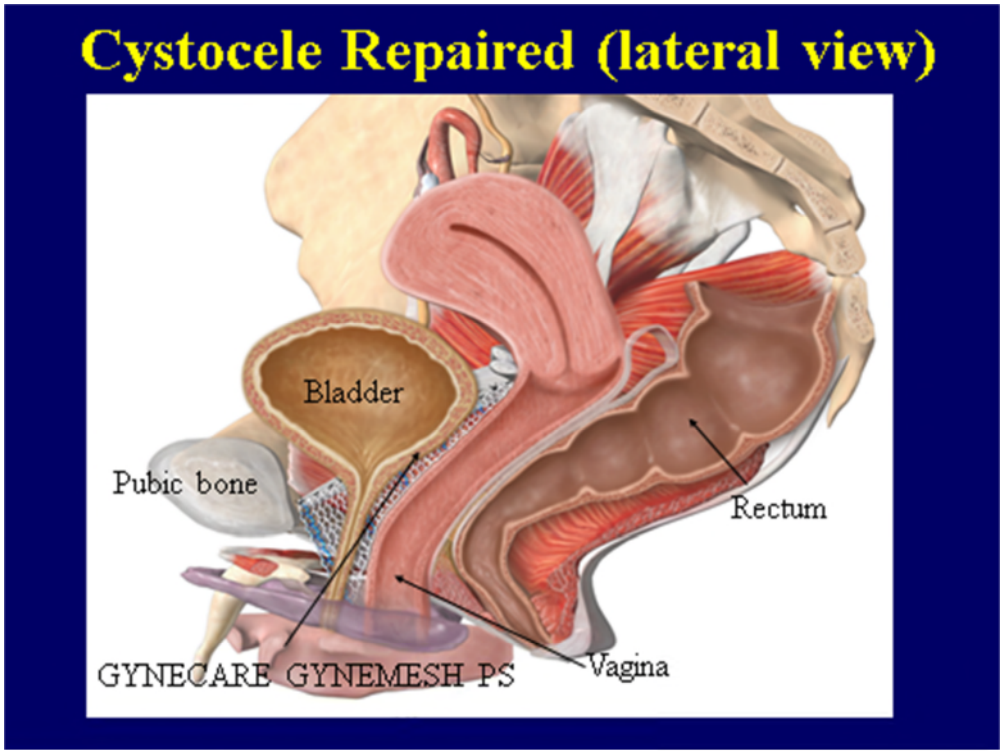
Gynecare Gynemesh PS

GYNECARE GYNEMESH PS
Cystocele Repair Literature/Study Review

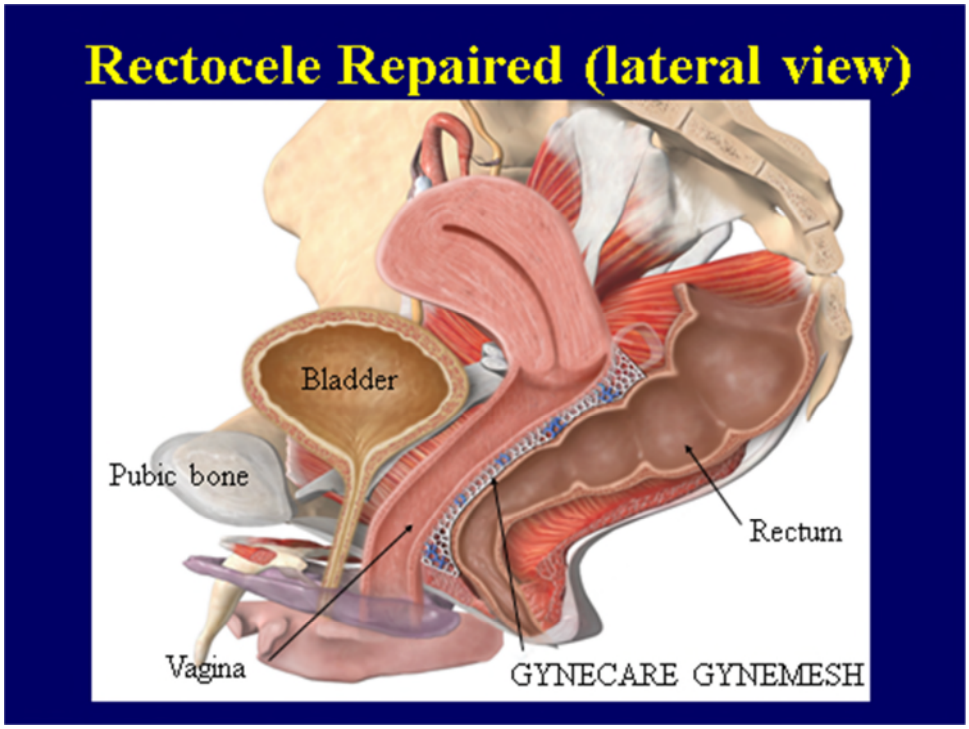
Type of Study	Author	Mean Follow-Up	Erosion Rate	Success
Prospective 88 Patients[1]	Lucente et al	12 months	9%	84%
Retrospective 687 Patients[2]	Jacquetin et al	3.6 months	7%	95%

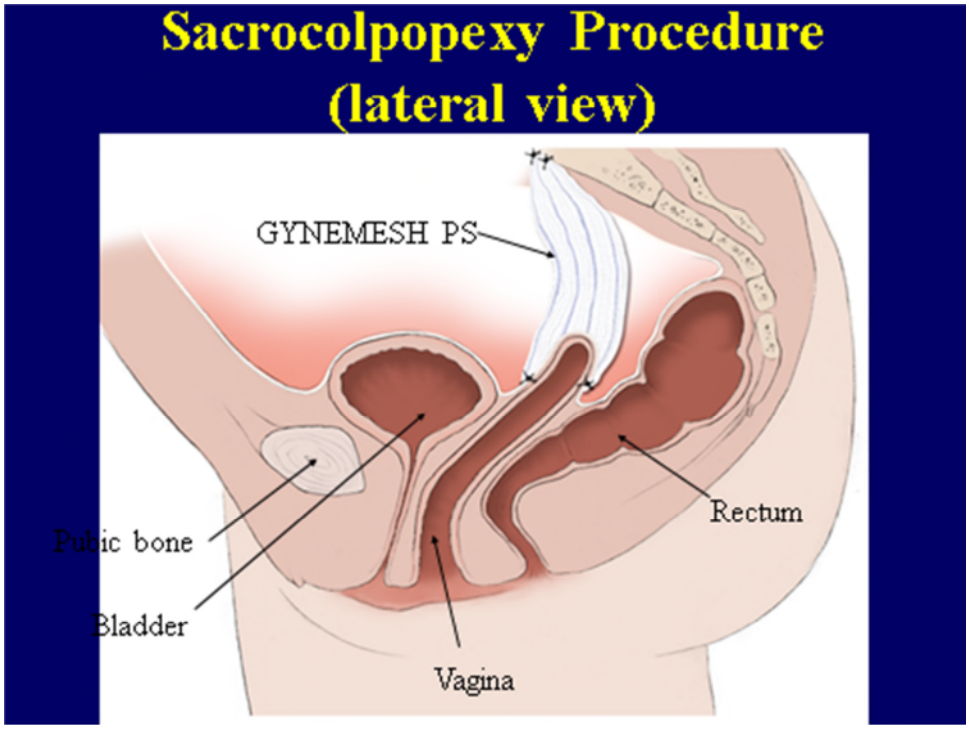
[1] Data on file ETHICON, Inc.
[2] Cosson et al. Neurourol Urodyn 2005;24(5/6):590

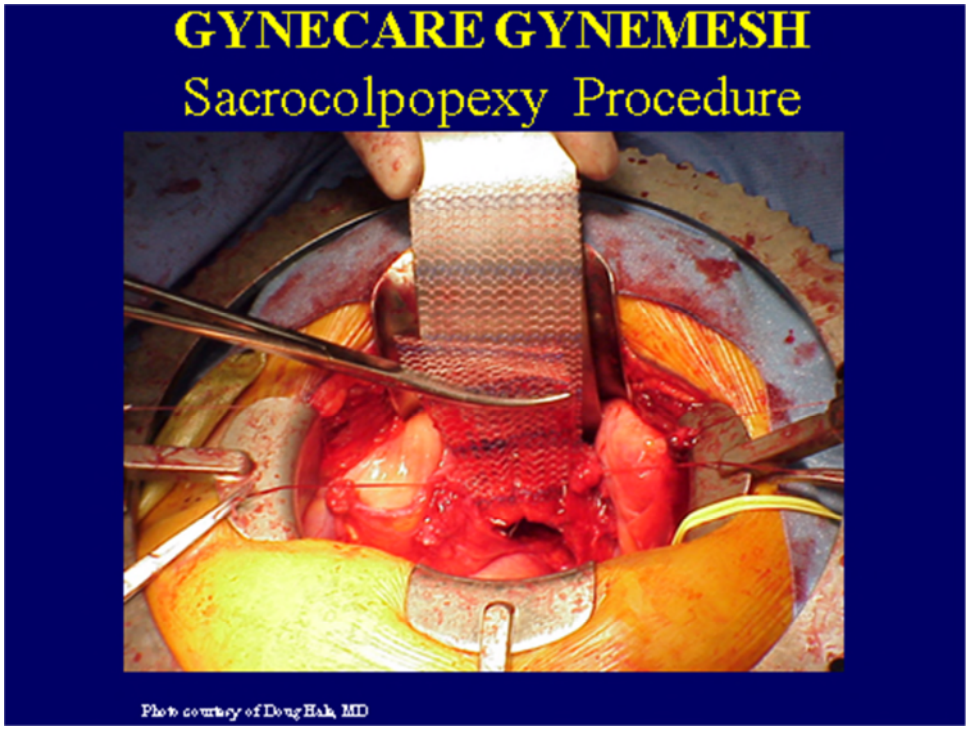
Gynecare Gynemesh PS


Cystocele Repaired (lateral view)
Bladder
Pubic bone
Rectum
GYNECARE GYNEMESH PS
Vagina


GYNECARE GYNEMESH
Cystocele Repair (surgical view)
Photo courtesy of Vincent Lucente, MD


Rectocele Repaired (lateral view)
Bladder
Pubic bone
Rectum
Vagina
GYNECARE GYNEMESH


Sacrocolpopexy Procedure
(lateral view)
GYNEMESH PS
Rectum
Pubic bone
Bladder
Vagina

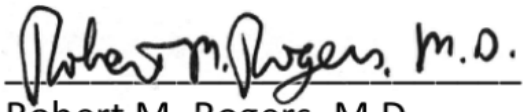


The plaintiffs' experts assert that polypropylene mesh causes an intense, chronic inflammation. However, animal and human studies indicate that polypropylene mesh has a low degree of inflammatory reaction (Krambeck et al., Urology, 2006; Falconer et al., Int Urogynecol J, 2001; Elmer et al. J Urology, 2009). The plaintiffs' experts assert that shrinkage of the mesh occurs. The IFU (Ethicon, 2003) states that, "Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing GYNECARE GYNEMESH PS for pelvic reconstruction." The IFU further states, under 'Adverse Reactions,' Potential adverse reactions include, "…extrusion and scarring that results in implant contraction." When a mesh is incorporated into ingrowing scar tissue, the scar itself tends to contract and shrink, not the mesh itself. It is a well known part of the normal healing process for nonmesh surgeries to result in scarring and tissue contracture, which can occasionally cause temporary or long-term pain and/or dyspareunia. In one study of 524 patients, severe symptomatic retraction occurred in 0.4% of patients. (de Landsheere et al., Am J Obstet Gynecol 2012). Criticisms of pain in the vagina from mesh are not substantiated,

since chronic pain can and does result from time to time with any reparative vaginal surgery due to the unanticipated formation of scar neuromas in healing vaginal incisions, especially apically.

Criticism of defective design of Gynemesh PS is not substantiated by clinical studies. Mesh related complications have been reported from 2.5% of 1882 patients (Jacquetin, Cosson, Int Urogynecol J, 2009) to 3.6% of 524 patients followed for 3 years (de Landsheere et al., Am J Obstet Gynecol 2012).

DATED: June 3, 2016



Robert M. Rogers, M.D.